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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,101	01/21/00	GURE	A L0461/7073(J

HM12/0621

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EXAMINER	
PENN, M	
ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 06/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/489,101	Applicant(s) GURE ET AL.	
	Examiner Christopher Drabik	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *7,16,50,52,63,65,70-72,78-80,85,88,98,102,109,and 115* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 117-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,2,7,16,50,52,63,65,70-72,78-80,85,88,98,102,109,115 and 117-127.

DETAILED ACTION

Claims 1, 2, 7, 16, 50, 52, 63, 65, 70-72, 78-80, 85, 88, 98, 102, 109, 115, and 117-127 are pending in the instant office action.

Election/Restrictions

Applicant's election without traverse of **Invention I, claims 1 and 2**, in Paper No. 9 is acknowledged. Applicant failed to elect a species, however, as required in Paper No. 9. During a telephone conversation with John Van Amsterdam on June 5, 2001, a provisional election was made without traverse to prosecute species of **NA Group I Nucleic Acid molecules**. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 7, 16, 50, 52, 63, 65, 70-72, 78-80, 85, 88, 98, 102, 109, and 115 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claims 1, 2, and 117-127 are under consideration in the instant office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the

list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 117-127, as best understood, is readable on a genus of fragments of NA group I nucleic acid molecules, wherein none of the identifiers or molecules are claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed application provides description of NA group I nucleic acid molecules. However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential fragments containing unspecified molecular structures/sequences of molecules that are essential for the making the genus fragments of NA group I nucleic acid molecules as claimed;

what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of fragments of NA group I nucleic acid molecules that must exhibit the disclosed biological functions as contemplated by the as-filed specification.

It is not sufficient to support the present claimed invention directed to fragments of NA group I nucleic acid molecules, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any and/or all other fragments of NA group I nucleic acid molecules having the biological functions as contemplated by the specification and the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures/sequences of fragments of NA group I nucleic acid molecules that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed

structure/sequence of a genus of the claimed fragments of NA group I nucleic acid molecules that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 1, 2, and 117-127 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of NA Group I nucleic acid molecules that hybridize to NA Group I nucleic acid molecules in a biological sample from a subject, does not reasonably provide enablement for any and all fragments thereof that hybridize to NA Group I nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 2 is drawn to methods of using nucleic acids to diagnose a disorder characterized by the expression of human cancer associated antigen precursors coded for by a nucleic acid molecule. The specification teaches the hybridization of NA group I nucleic acid molecules to NA group I nucleic acid molecules in a biological sample isolated from a subject (p. 17, line 30). The specification further contemplates the use of unique fragments of NA group I nucleic acid molecules, describes in vague terms what these unique fragments can consist of, and discusses ways to decide upon which sequences to utilize (p. 19, line 22). However, the specification does not specifically teach the use of any and all fragments of NA group I nucleic acid molecules. Since claim 2 is not supported by a written description for possessing the genus of "fragments thereof" as recited, one skilled in the art would not have known how to use and make the claimed invention so that it would operate as intended, i.e. as a diagnostic agent, without undue and burdensome experimentation.

Furthermore, "fragment thereof" could encompass any number of mutated or truncated forms of the desired polynucleotide, including merely a single nucleic acid base pair. The hybridization of only one nucleic acid base pair would clearly not yield the method results as claimed. Accordingly, because of the sheer number of possibilities, at the time of filing one skilled in the art would not be able to predict that the use of every and all possible nucleic acid fragments would function as intended without undue experimentation.

Claims 1, 2, and 117-127 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The pending claims of the instant application are drawn to methods for using nucleic acids to diagnose a disorder characterized by the expression of human cancer associated antigen precursors. The art surrounding cancer antigens is still developing, and is therefore still unpredictable. The specification teaches that the NA group I nucleic acid molecules can be used as a diagnosis method for detecting cancer associated antigen precursors (page 15, line 26). However, merely because these nucleic acid molecules hybridize to the sequences in cancer cells, or cells associated with a disorder that is characterized by expression of these antigens, does not mean that it will function as a reliable method of diagnosis for cancer or other disorders. Many

of the cancer associated antigen precursors are not uniquely expressed in cancer cells, or cells associated with a disorder. Often these antigens are expressed in embryonic tissue, developing tissue, or proliferating tissue such as in tissue undergoing the repair process. In a review of cancer vaccines, Pardoll (Pardoll, Nat. Med., May 1998, pp. 525-531) teaches that tissue specific differentiation antigens are not only expressed in the tumor cells, but also in the cells from which the tumor arose (p. 526, 1st col., 4th paragraph). This is exemplified by the Mart-1, tyrosinase, and gp100 melanoma antigens, which are expressed in differentiated melanocytes as well as melanoma (Pardoll, p. 526, 2nd col., 5th paragraph). Other examples would include the NA group I nucleic acid molecule Id4, which was isolated from adipose tissue (see GenBank U28368), and soxl, which was isolated from the developing brain (see GenBank Y13436), both of which are listed in the specification of the instant application. For these reasons, it is not clear that one could reliably diagnose cancer or other disorders using methods based on detection of cancer associated antigen precursors.

Therefore, considering the unpredictability of the art of cancer antigen precursors, the limited guidance provided in the specification, the limited scope of working examples and lack of enabling data, it would have required one of skill in the art at the time of filing undue experimentation to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, and 117-127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of an agent (nucleic acid) that "specifically binds" to an NA group I nucleic acid molecule. The specification describes "stringent conditions" in referring to nucleic acid hybridization, with specific conditions being detailed (p. 16, line 31). However, it is unclear what is meant by the use of the word "specifically," and how it relates to the methods described in the specification. Claim 2 depends on claim 1, as do claims 117-127, and they do not further clarify claim 1. Clarification is necessary.

No claims are allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Penn who can normally be reached on Monday through Friday from 8:00 am to 4:30 p.m. at (703) 308-2454.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, who can normally be reached on Monday through Friday from 9:00 am to 5:30 p.m. at (703) 305-3015.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

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